

CLAIMS

1) Implantable device for the measurement of the physical properties of the pulmonary tissue depending from its density, characterised by comprising:

- At least an intrapulmonary catheter (2) suitable to be inserted in a branch of the pulmonary artery;

- At least a sensor of density dependent physical properties of the pulmonary tissue, located at least inside said intrapulmonary catheter;

- Means for assessing the density dependent physical properties of the portion of pulmonary tissue explored by said intrapulmonary catheter provided with sensors (2);

- Means for processing the measure of the physical properties of the pulmonary tissue depending from its density and their variations, for diagnostic and/or therapeutic purposes, said measurement and elaboration means being placed inside an implantable container (1), to which is connected said catheter provided with sensors (2) and which contains the suitable means for the electric feeding.

2) Implantable device according to claim 1), in which the sensor for the density depending physical properties, comprises heat flow sensors, to detect the variations of the thermal conductivity of the pulmonary tissue when there is a variation in the fluid accumulation.

3) Implantable device according to claim 1) in which the sensor for the physical properties which are depending from the density of the pulmonary tissue, comprises optical sensors, to detect the transluminescence and/or colour variations of the pulmonary tissue at the variation of the fluid accumulation.

4) Implantable device according to claim 1), in which the sensor for the density dependent physical properties of the pulmonary tissue, comprises ultrasonic generators and relative means to detect the variations of the propagation velocity of the ultrasounds inside the pulmonary tissue, when there is a variation in the fluid accumulation.

5) Implantable device according to claim 1, in which the sensor/s of the density dependant physical properties of the pulmonary tissue comprises electrodes (3).

(6) Implantable device according to claim 1) in which the body of the container (1) of the same device is realised in electroconductive material which can be used as electrode and which can be involved in the measurement process for which the same device is prefixed.

5 (7) Implantable device according to claim 5) in which the means for the measurement of physical properties of the pulmonary tissue depending from its density, comprise means for the measurement, by means of said electrodes, the bioelectric impedance of the portion of pulmonary tissue explored by said catheter provided with sensors (2) and means for the processing of the obtained measure.

10 (8) Implantable device according to claim 5), in which the means for the measurement of the physical properties of the pulmonary tissue depending from its density, comprise means to detect the electrocardiogram (ECG) by means of said electrodes, means for the measurement of the amplitude of the R waves of the detected ECG and means for the processing of the detected measure.

15 (9) Implantable device according to claim 7) in which said means for the measurement of the bioelectric impedance, comprise also means to detect an electrocardiogram (ECG) by means of the electrodes of the same device and means for the processing of the detected ECG signal.

20 (10) Implantable device according to claim 7), in which said means for the measurement of the bioelectric impedance of a portion of pulmonary tissue by means of said electrodes, comprises means to generate in said portions of tissue several measurement electric currents and means for the measurement of the differences of potential which are the consequence of the application of said measurement currents and which are proportional to the required bioelectric impedance.

25 (11) Implantable device according to claim 5), in which the electrodes (1, 3) may be used, separated or in conjunction, with any suitable combination, for the application of said measurement electric currents and for the measurement of the differences of potential and of the bioelectric impedances which follows the application of said measurement currents.

30 (12) Implantable device according to claim 10), in which said electric measurement

currents are impulses and/or multiple and determined frequencies currents.

13) Implantable device according to claim 12, in which said measurement electric currents have components with frequencies comprise approximately between about 10 kHz and 1 MHz.

5 14) Implantable device according to claim 12), in which said means for the measurement of the differences of potential which follow to the application of said measurement currents and which are proportional to the required bioelectric impedances, comprise a differential amplifier (10), which amplifies the signals obtained between the electrodes of the same device, which are further filtered by a high-pass filter (11) and then processed by a sample and hold unit (13) and are finally digitised by means of a converter (14) before the transfer to the process unit (7).

15) Implantable device according to claim 14), in which the high-pass filter (11) works at about 1 kHz.

15 16) Implantable device according to claim 11), in which the measurement electric currents are applied between the two electrodes of the intrapulmonary catheter (2) and the differences of potential proportional to the bioelectric impedances are measured between the two same electrodes of the same catheter.

20 17) Implantable device according to claim 11) in which the measurement electric currents are applied between two electrodes of the intrapulmonary catheter and the differences of potential proportional to the bioelectric impedances are measured between two other electrodes of the same catheter.

25 18) Device according to claim 11), in which the measurement electric currents are applied between an electrode of a first intrapulmonary catheter and an electrode of a second intrapulmonary catheter and the differences of potential proportional to the bioelectric impedances are measured between another electrode of said first catheter and another electrode of the said second catheter.

30 19) Device according to claim 11), in which the measurement electric currents are applied between an electrode of a first intrapulmonary catheter and an electrode of a second intrapulmonary catheter and the differences of potential proportional to the

bioelectric impedances, are measured between the same electrodes of the two said catheters.

20) Implantable device according to claim 11), in which the measurement electric currents are applied between an electrode of the intrapulmonary catheter (2) and the electroconductive body of the same container (1) of the same device and the differences of potential proportional to the bioelectric impedances, are measured between another electrode of the same intrapulmonary catheter and the body of the container of the same device.

21) Implantable device according to claim 11), in which the measurement electric currents are applied between an electrode of an intrapulmonary catheter (2) and the electroconductive body of the container (1) of the same device and the differences of potential proportional to the bioelectric impedances, are measured between the two other electrodes of the same intrapulmonary catheter.

22) Implantable device according to claim 11), in which the measurement electric currents are applied between an electrode of the intrapulmonary catheter (2) and the electroconductive body of the container (1) of the same device and the differences of potential proportional to the bioelectric impedances, are measured between the same electrode of the intrapulmonary catheter and the body of the container of the same device.

23) Implantable device according to claim 11), in which the measurement electric currents are applied between an electrode of the intrapulmonary catheter (2) and the electroconductive body of the container (1) of the same device and between another electrode of the same intrapulmonary catheter, suitably spaced from the first electrode, and said body of the device, and the corresponding differences of potential proportional to the bioelectric impedances (Z_a , Z_b) are measured disjointly between the same electrodes and the body of the device and means (210) are provided to obtain the bioelectric pulmonary impedance (Z_c) as a difference between the two said obtained measures (Z_a , Z_b).

24) Implantable device according to claim 10, in which the means for the detecting of the ECG comprise a differential amplifier (10) to amplify the signals detected by

the measurement electrodes and comprise a band-pass filter (12) connected to the output of said differential amplifier.

25) Implantable device according to claim 24) in which the pass band filter (12) operates preferably between 0,01 and 100 Hz.

5 26) Implantable device according to claim 8), in which said means for the measurement of the amplitude of the R waves of the ECG comprise a differential amplifier (10) to amplify the signal detected by the measurement electrodes of the ECG, comprise a band-pass filter (112) which acts preferably between 10 and 60 Hz and comprise a sampling unit of the type sample and hold (13').

10 27) Implantable device according to claim 14, characterised by comprising a conversion unit (14) to digitise the analog output signals from the sample and hold (13, 13') and relative to the bioelectric impedance or to the R wave of the electrocardiographic signal and in output from the band-pass filter (12) which provides the electrocardiographic signal (ECG), the output of said conversion unit being connected to a processing unit (7) which provides the required temporal control to said sampling unit (13) and to the converter (14), which is assisted by a ROM (15) and RAM (16) memory unit which provide respectively the processing algorithms and which register the measured and processed data, comprehensive of the possible identification of alarm situations, said processing unit being connected to a break-in
15 radio-frequency unit (17) with its antenna (117).

20 28) Implantable device according to claim 1) characterised by comprising external radio-frequency means (4, 104) by means of which the same device can be enquired and can be programmed for the diagnostic and/or therapeutic functions, also with the predisposition of alarm thresholds.

25 29) Implantable device according to claim 6), in which the processing means for the detected bioelectric impedance, comprise any mathematics elaboration means of the signal to detect at least the minimum and maximum values, the peak to peak amplitude, the medium value, the period, the derivate and the finite integral.

30 30) Implantable device according to claim 9), in which the processing means of the electrocardiogram (ECG) comprise any mathematics elaboration means of the

signal to detect at least the minimum and maximum values, the peak to peak amplitude, the medium value, the period, the derivate and the finite integral.

31) Implantable device according to claim 9), in which said processing means comprise means to measure the bioelectric impedance in a pre-determined temporal relation with the electrocardiographic signal (ECG).

32) Implantable device according to claim 9), in which said processing means comprise means to determine the respiratory parameters, among which the respiratory frequency, the speed and the volume of the respiration and the ventilation per minute.

33) Implantable device according to claim 32), in which said processing means comprise means for the analysis of the bioelectric impedance in correspondence of pre-determined temporal phases of said respiratory parameters.

34) Implantable device according to claim 32), in which the processing means comprise any calculating means to detect the posture variations of the patient in relation to the bioelectric impedance variations.

35) Implantable device according to claim 32), in which said processing means comprise any calculating means to detect the posture variations of the patient in relation to the ECG variations.

36) Implantable device according to claim 32), in which said processing means comprise means which detect the posture variations of the patient in relation to the variations of the ECG and in function of the bioelectric impedance variations.

37) Implantable device according to claim 32), in which the processing means of the ECG comprise calculating means to detect the normal or pathologic of the heart due to heart failure, ischemia or arrhythmia.

38) Implantable device according to claim 1) characterised by comprising a postural sensor inside of the container (1) of the same device.

39) Implantable device according to claim 34), in which said processing means comprise means to detect the variation of the bioelectric impedance in function of the posture variations.

40) Implantable device according to claim 34), in which said processing means

comprise means to detect the electrocardiogram (ECG) variations in function of the posture variations.

41) Device according to claim 1), characterised by comprising means to verify if the measured physical property depending from the density of the pulmonary tissue exceeds programmed threshold values or basal reference values and to generate consequent alarm signals, to activate the same device in the therapeutic and/or diagnostic function.

42) Implantable device according to claim 1), characterised by comprising means which in function of the measured physical properties, which depend from the density of the pulmonary tissue, and in function of the variations of said physical properties, provide to exhibit to the patient a pre-established therapy.

43) Implantable device according to claim 42), in which said therapy comprises the activation of means for the electrostimulation of the heart.

44) Implantable device according to claim 42), in which said therapy comprises the activation of means for the electric defibrillation of the heart.

45) Implantable device according to claim 42), in which said therapy comprises the activation of systems for the releasing of drugs.

46) Implantable device according to claim 42), in which said therapy comprises the activation of systems for the drainage of fluids accumulated in the body.

47) Implantable device according to claim 42), in which said therapy comprises the activation of means for the mechanical circulatory assistance to the heart.

48) Implantable device according to claim 42), in which said therapy comprises the activation of means for the stimulation and/or the electric defibrillation of the heart and/or for the exhibition of drugs and/or for the drainage of the fluids accumulated in the body and/or for the mechanical circulatory assistance to the heart.

49) Method to detect the physical properties of the pulmonary tissue depending from its density and their variations, characterised by the sequence of the following operative phases:

- Insertion through the intravenous way and through the heart, of at least one intrapulmonary catheter with at least a pulmonary density sensor, in a branch of the

pulmonary artery, to reach the lung, and subcutaneous insertion of the container which contains the several feeding and processing means and to which said intrapulmonary catheter provided with sensors is connected;

- Control and programming of the implanted device by means of external means which can be connected by telemetric way with the same implanted device;
- Detection, by means of said intrapulmonary catheter provided with sensors, of the variations of the physical properties of the pulmonary tissue which are depending by its density, and utilisation of the results of the observation for diagnostic and/or therapeutic purposes.

10 50) Method according to claim 49), characterised by the fact that if the implantable device is provided with more catheters provided with sensors, the same catheters are placed in a same lung, in a position sufficiently spaced the one for the other.

51) Method according to claim 49), in which the intrapulmonary catheter/s provided with sensors of the implantable device are preferably placed in the right lung.